UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,647	07/30/2003	Junya Yoneda	239534US0CONT	6857

22850 7590 04/07/2008

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
SOROUSH, LAYLA	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
04/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/629,647	YONEDA ET AL.	
	Examiner	Art Unit	
	LAYLA SOROUSH	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,22-28 and 30* is/are pending in the application.

4a) Of the above claim(s) *1-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-20 and 22-28* is/are rejected.

7)☒ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed January 4, 2008 presents remarks and arguments submitted to the office action mailed October 5, 2007 is acknowledged.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 14-17, 20, 22-25, 28 over Burgstiner (WO 98/18491) as evidenced by Moretti (WO 97/05862 – previously presented), Meisner (US Pat No. 4,772,591– previously presented) and Bryan (6,274,612) is persuasive due to amendments made to the claims. However, the rejection is modified to address the newly amended limitations.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 18, 19, 26, and 27 over Burgstiner (WO 98/18491) in view of Moretti (WO 97/05862 – previously presented), Meisner (US Pat No. 4,772,591– previously presented) and Bryan (6,274,612) as applied to claims 14-17, 20, 22-25, 28 above, and further in view of Fischer et al. (US Pat. No. 3,950,529—previously presented) and Ansel et al. (Pharmaceutical Dosage Forms and Drug Delivery Systems 7th Edition p 227—previously presented) is persuasive due to amendments made to the claims. Thus, the rejection is modified to address the newly amended limitations.

Claims 1-13, 14-20, 22-28 and 30 are pending.

Claims 14-20, 22-28 and 30 are herein acted on the merits.

Examiner has inadvertently excluded claims 26 and 27 from the 35 USC § 103 obviousness rejection statement. However, the limitations of claims 26 and 27 were addressed in the rejection made on October 5, 2007. Hence, the 35 U.S.C. 103 (a) rejection of claims 18, 19, 26, and 27 were all made in view of Burgstiner (WO

98/18491), Moretti (WO 97/05862 – previously presented), Meisner (US Pat No. 4,772,591– previously presented), Bryan (6,274,612), Fischer et al. (US Pat. No. 3,950,529—previously presented), and Ansel et al. (Pharmaceutical Dosage Forms and Drug Delivery Systems 7th Edition p 227—previously presented).

The rejection of record is modified below addressing the newly amended limitations:

Claim Objections

Claim 30 is objected to as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-17, 20, 22-25, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Burgstiner (WO 98/18491 – previously presented) as evidenced by Moretti (WO 97/05862 – previously presented), Meisner (US Pat No. 4,772,591– previously presented) and Bryan (6,274,612).

Burgstiner teaches a composition and dietary supplementation (p 21 lines 5-15) comprising thymic-derived factors and enzymatic co-factors, wherein the thymic-derived factors can be thymus extract, thymus enzymatic polypeptide factors, thymosin, thymopoietin and thymic humoral factor and the enzymatic co-factors can be vitamins A,

C, D, E, B-1, B-2, B-6, B-12, minerals, amino acids which can be arginine, cysteine, histidine, L-ornithIne, L-isoleucine, L-leucine, threonine, tyrosine, L-valine, phenylalanine and methionine. The reference teaches treatment autoimmune disease inclusive of rheumatoid arthritis in a subject comprising administering to the subject the compositions of the present invention (page 33, claim 10, 15, and 16). The composition can be formulated into any type of dosing system, such as a tablet, captab, in liquid or injections for topical transdermal, oral, rectal, or parenteral routes (page 24, line 5-20).

Moretti is solely incorporated to show that the oral or parenteral administration of the amino acid ornithine in the treatment of inflammatory bowel disease, hepato-splenomegaly associated with inflammatory disease, rheumatoid arthritis, and connective tissue disease (inflammatory diseases) (see claims 1,2,4,12-14, and 15; p. 9-11).

Meisner is solely incorporated to show that an amino acid used in a composition to treat tissue degenerative inflammations and inflammatory diseases is valine (branched amino acid) (column 4, lines 42-60). Exemplary inflammatory diseases include osteoarthritis. The composition is administered topically and orally (column 6, lines 15 and 40). In the oral form, the substance mixture is formulated into pharmaceutically acceptable dosage forms such as powders, tablets, or capsules (see column 6, lines 45-49).

Bryan is solely incorporated to show that a method of administering an amino acid protocol at least one essential amino acid such as Isoleucine, Leucine, Lysine,

Methionine, Phenylalanine, Threonine, Tryptophan and Valine (col. 8, claims 1-3) is useful in treating an autoimmune disease inclusive of rheumatoid arthritis in a patient suffering therefrom.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For art purposes, "the consisting essentially of" language in the claim is treated as "comprising" language and it is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language." (See MPEP 2111.03)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18, 19, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgstiner (WO 98/18491) in view of Moretti (WO 97/05862 – previously presented), Meisner (US Pat No. 4,772,591– previously presented) and Bryan (6,274,612) as applied to claims 14-17, 20, 22-25, 28 above, and further in view of Fischer et al. (US Pat. No. 3,950,529—previously presented) and Ansel et al. (Pharmaceutical Dosage Forms and Drug Delivery Systems 7th Edition p 227—previously presented).

Burgstiner, Moretti et al., Meisner and Bryan is as discussed above.

Burgstiner, Moretti et al., Meisner and Bryan fail to teach ornithine and a branched amino acids in a food or a drink.

Fischer teaches an amino acid formulation comprised of isoluecine, leucine, and valine formulated for intravenous or oral administration (see abstract). For oral consumption, the amino acid mixture, are made into edible food preparations in the form of palatable liquid drinks or semisolid foods.

Additionally, Ansel et al. teaches, "solid dosage forms are best taken with a glassful of water or a beverage. Further, the reference teaches an ordinary tablet crushed or a capsule opened helps "facilitate ease of administration, any unpleasant drug taste may be masked by mixing with custards, yogurt, rice pudding, other soft food, or fruit juice (p. 227, column 2, paragraph 5)."

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer ornithine and branched amino acids with a food or

drink because Morreti et al. teaches amino acid compositions comprising leucine, isoleucine, and valine incorporated with food preparations. The motivation to administer ornithine and branched amino acids with a food or drink is because Ansel et al. teaches that for ease of administration and avoidance of unpleasant tastes drugs may be administered with various foods and drinks. Therefore, a skilled artisan would have reasonable expectation of success in incorporating ornithine and branched amino acids with a food or drink.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For art purposes, "the consisting essentially of" language in the claim is treated as "comprising" language and it is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language." (See MPEP 2111.03)

Response to Arguments

Applicant's arguments filed on January 4, 2008 have been fully considered.

Applicant submits that "the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461,463 (CCPA 1976). None of Burgstiner, Moretti, Meisner, and Bryan disclose or suggest a composition consisting essentially of an effective amount of ornithine and at least one branched amino acid as presently claimed or the advantages flowing therefrom." If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). (MPEP 2163 (i)).

The arguments are not persuasive and the rejection is made **FINAL**.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617